201-15597

Roche

July 19, 2000

William H. Sanders III, 7401
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
USEPA Headquarters
Ariel Rios Building
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Mr. Sanders:

This correspondence pertains to the listing of natural vitamin E (d-α-tocopherol, Chemical Abstracts Registry Number 59-02-9) as a High Production Volume (HPV) chemical. Hoffmann-La Roche Inc. would like to work with you to remove this material from the HPV list, so that EPA and industry resources can be focused on HPV chemicals that possess a greater potential to pose risks to human health and the environment.

Only two companies made non-confidential natural vitamin E submissions in response to the 1990, 1994 or 1998 Toxic Substances Control Act (TSCA) Inventory Update Rules (IUR), Eastman Chemical Company and Henkel Corporation. Hoffmann-La Roche Inc. contacted Henkel and learned that the company reported natural vitamin E that was imported or manufactured for uses subject to the Food, Drug and Cosmetic Act in response to the 1990 TSCA IUR.

Natural vitamin E is nearly exclusively marketed for use in foods, drugs or cosmetics, uses regulated under the Federal Food, Drug and Cosmetic Act (FDCA). As long as it is marketed for these uses, the import or manufacture of natural vitamin E falls outside the Toxic Substance Control Act definition of a "chemical substance" and is not subject to TSCA. TSCA Inventory Update Reporting of the amounts of natural vitamin E imported or manufactured for food, drug or cosmetic uses regulated under FDCA are therefore not relevant to the HPV program, and should not be used in calculating the production volumes used in turn to determine HPV program applicability.

Eastman Chemical Company reported import or manufacture of natural vitamin E to the 1994 IUR, but no longer manufactures or imports it. If any other companies reported importing or manufacturing natural vitamin E in response to the 1990, 1994 or 1998 IUR, they did so claiming that this information is confidential, in which case their identities cannot be divulged to third parties.

Hoffmann-La Roche Inc. believes that when companies that no longer import or manufacture natural vitamin E are identified and document their current production status, natural vitamin E will be verified as no longer HPV. Additionally, if the natural vitamin E imported or manufactured for uses regulated under the FDCA and inadvertently reported in response to one or more IUR is removed from the total

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production volume, there is an even smaller probability that the remaining production volume will be sufficient to justify allowing it to remain in the HPV program.

Eastman and Henkel have both indicated to Hoffmann-La Roche that they are willing to send letters to you documenting their current status with regard to the import or manufacture of natural vitamin E so that the production volume of this material can be more precisely estimated.

We urge you to contact the companies who confidentially reported the import or manufacture of natural vitamin E to the 1990, 1994 or 1998 IUR and request that they provide new estimates of their production volume specifically to determine HPV program applicability. Please explain the FDCA use consideration outlined above and afford these companies another opportunity to provide accurate current data.

Sincerely,

Stanley S. Rodgers
Senior Environmental, Health & Safety Professional
Corporate Environmental & Safety Affairs

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